Marengo Announces First Patient Dosed in Phase 2 Clinical Study for its Lead Program, Invikafusp Alfa (STAR0602) in PD-1 Resistant Tumors, Expands Study to Europe

- *Phase 1 STARt-001 data demonstrated a 25% Overall Response Rate and 50% Disease Control Rate observed at the targeted dose range during the Phase 1 investigation in patients harboring PD-1 resistant tumors with high tumor mutation burden, including confirmed responses in microsatellite-stable colorectal cancer*

- *Global Phase 2 study has expanded from North American (US and Canada) sites to premier European oncology clinical research centers, with initial activation of study sites in France and Spain*

Cambridge, Mass., December 20, 2024 – Marengo Therapeutics, Inc., a clinical-stage biotechnology company pioneering novel approaches for precision T cell activation, today announced the dosing of the first patient in the Phase 2 portion of its STARt-001 trial. The clinical study builds on the Phase 1/2 trial evaluating invikafusp alfa as a monotherapy in biomarker-enriched patients with advanced anti-PD-1 resistant solid tumors.

The results of the Phase 1 portion of the STARt-001 trial were recently presented during a plenary late-breaking oral session at the SITC Annual Meeting and an oral presentation at the 2024 ESMO Immuno-Oncology Congress. The data collectively validate Marengo's STAR platform design and demonstrate early single agent anti-tumor activity of invikafusp alfa (STAR0602), including clinical benefit in heavily pre-treated, anti-PD-1 resistant cancer patients. Invikafusp alfa exhibited a manageable safety profile consistent with its novel mechanism of action, reinforcing its potential as a treatment option across high tumor mutation burden (TMB-H) cancers or virally associated malignancies.

The Phase 2 clinical trial will treat patients with the RP2D (0.08mg/kg) and is now enrolling patients in Europe at leading oncology centers, with initial activation of sites in France and Spain.

"We are thrilled to advance invikafusp alfa into Phase 2 with the addition of premier European oncology centers," said Ke Liu, M.D., Ph.D., Chief Development Officer of Marengo Therapeutics. "The single-agent anti-tumor activity observed in Phase 1, particularly in PD-1-resistant 'cold' tumors like colorectal cancer, gives us confidence in our approach and fuels our hope to reach as many patients as possible. The addition of renowned European institutions expands our geographical footprint and enhances our ability to enroll more PD-1 resistant patient populations. Through our Phase 2 study, we aim to deepen our understanding of invikafusp alfa's mechanism of action across diverse tumor types."

About Marengo Therapeutics

Marengo Therapeutics, Inc, a clinical-stage biotech company, develops novel TCR-targeting antibodies that selectively modulate common and disease-specific T cell subsets of the germline TCR repertoire to provide lifelong protection against cancer and other diseases. With a passionate team of dedicated scientists experienced in immunology and oncology, Marengo's

proprietary Selective T Cell Activation Repertoire (STAR) platform leverages an extensive biological understanding of T cell function and receptor signaling to create a world in which everyone's immune system can defeat cancer. To learn more, visit marengotx.com.

About the STAR™ Platform
Marengo's STAR™ Platform is a multi-specific antibody-fusion platform derived from Marengo's proprietary library of antibodies targeting germline-encoded variable Vβ regions of the TCR fused to different T cell co-stimulatory moieties. Combining a novel non-clonal mode of TCR activation with a T cell co-stimulator in the same molecule, promotes a distinct mechanism of action that promotes durable anti-tumor Vβ T cell responses.

About invikafusp alfa (STAR0602)
Invikafusp alfa (STAR0602) is Marengo's lead program, and the first T cell activator generated from Marengo's STAR platform; a library of antibodies targeting non-clonal variable Vβ regions of the TCR fused to different co-stimulatory moieties. STAR0602 selectively targets a common Vβ T cell subset present in all cancers and, by combining a novel non-clonal mode of TCR activation with a T cell co-stimulator in the same molecule, promotes expansion of a new population of clonally enriched, effector memory Vβ T cells that turbo-charge tumor immune responses and promote durable clearance of tumors. STAR0602 has undergone extensive preclinical testing and is currently being studied in a Phase 1/2 clinical trial.

About the STARt-001 trial
Clinical Study STARt-001 is a Phase 1/2 clinical trial evaluating the safety, tolerability, and preliminary clinical activity of invikafusp alfa (STAR0602) as a single agent in biomarker selected patients with advanced antigen-rich solid tumors including PD-1 refractory and rare tumors. This open-label, multi-center trial consists 2 of two parts: Phase 1 dose escalation and Phase 2 dose expansion. For more information, please visit clinicaltrials.gov (trial identifier: NCT05592626).

For patients interested in enrolling in this study at NCI, please contact NCI's toll-free number 1800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615) and/or the website https://trials.cancer.gov and/or email NCIMO_referrals@mail.nih.gov.

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